LASENTEC®

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October 7, 1993

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Dr.
Rockville, MD 20857



Re.: Docket No. 93 N-0044

Dear Sir/Madam:

I am writing with regards to your proposed amendments to 21 CFR Part 1040. 10(d). My company is a manufacturer of industrial sensors that use infra-red laser diodes as a source of light. We are selling these devices not only in the USA but also in Europe and Japan.

We greatly applaud your efforts to bring the USA standards in conformance with the safety standards established by other agencies around the world. It has been our experience that the much tighter USA regulations have put our products at a great disadvantage when we are trying to compete in the international arena. Furthermore, we can cite several examples of competitors offering their products on the USA market, without subjecting themselves to the same rigorous inspection and reporting procedures all US manufacturers are required to do.

We appreciate your efforts in this regard and support raising the AEL (in the 500-1,400 nm range) as warranted by the most recent biological test results. If we can be of any help in your efforts to set new, more realistic AEL levels, please feel free to contact us.

With best regards

Ekhard Preikschat, Ph. D., P.E.
President

93N-0044 C19

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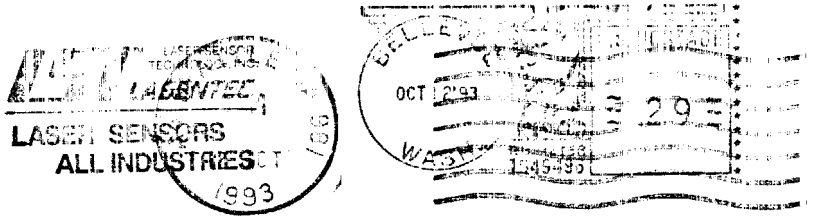


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